

Remarks

Claims 1-17 are pending in the subject application. Claim 4 has been withdrawn as pertaining to non-elected subject matter. Applicants note that claim 4 should be reconsidered for examination upon the allowance of a generic linking claim. Accordingly, claims 1-3 and 5-17 are before the Examiner for consideration.

Claims 1, 2, 5, and 6 are rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,899,349 ('349 patent). Applicants respectfully traverse. The '349 patent pertains to a pulse oximeter with an offset LED/photodetector for use on thin tissue areas. The Office Action refers, in particular, to the probe (40) shown FIG. 9 of the '349 patent. Applicants believe that a careful analysis of the probe 40 reveals that such probe lacks several features recited in claim 1.

Probe 40 is in actuality a clamp (or 'gripper') design. It comprises a U-shaped clamp (120) having two ends, where one end comprises a LED portion 122 and the other other end comprises photodetector portion 124. The probe 40 is designed to clamp the LED and photodetector onto a tissue: "the gripper 40 includes a housing 120 which, in an at rest configuration, positions the emitter engagement portion 122 into contact with the detector engagement portion 124 (Col 9, lines 60-65).

Probe 40 does not comprise a proximal arm and distal arm as recited in claim 1. The proximal arm of claim 1 is the arm that is outside the patient's mouth and the distal arm is the arm that resides on the inside of the mouth. The clamp design of probe 40 does not have any particular arm that could be considered proximal or distal, which is not surprising because nowhere does the '349 patent discuss the use of such probe on the lip or cheek of the patient. Probe 40 does not comprise conductors that pass within the probe frame 120 and out from the probe frame into a cable, much less out from the probe frame and into a cable connected to the proximal arm. Probe 40 simply does not teach that conductors pass through the frame out one of the probe arms into a cable. As will be discussed in further detail below in response to the obviousness rejections, the exit of the

conductors out of the probe frame is critical for the proper operation of the probe at the patient's lip or cheek.

As noted above, the '349 patent does not disclose all of the elements of claim 1 as required for anticipation. Claims 2, 5, and 6 are construed to include the limitations of claim 1, and therefore similarly are not anticipated by the '349 patent. Applicants respectfully request reconsideration of this 35 USC § 102(b) rejection.

Claim 3 is rejected under 35 USC § 103(a) as being obvious over the '349 patent in further view of U.S. Patent No. 5,817,008 ('008 patent). Applicants respectfully traverse and incorporate the remarks made above in reply to the anticipation rejection. Claim 3 is construed to contain the limitations of claim 1. Applicants reiterate that the '349 patent does not disclose a probe having conductors that pass within the probe frame and does not teach a cable attached to a proximal arm. Applicants also reiterate that the '349 patent does not contemplate the placement of a pulse oximeter probe on the lip or cheek of a patient. It is clear that the probe 40 of the '349 patent could not legitimately be used on the lip or cheek of a patient. The wires of the probe 40 are oriented such that they extend at an oblique angle to the space defined by the frame 120. In all fairness, this arrangement would not work for placement of the probe 40 over a patient's lip or cheek. The wires would extend into the person's mouth, making placement of the probe on the lip or cheek nearly impossible, and undoubtedly cumbersome and uncomfortable. There is no suggestion or teaching to modify the configuration of the probe 40 taught by the '349 patent.

Applicants also point out that the configuration of probe 40 is designed for clamping onto a tissue. As noted above, even in a resting position, the detector portion and light emitter portion are brought into contact with each other. For prolonged use, or even short term use, the pinching of the tender cheek and lip tissue is at best, uncomfortable, and at worse can cause ulceration on the face of the patient. Applicants note that even slight pressure on these tender tissues, if left on the lip or cheek for sustained periods of time, will lead to ulceration. The '349 patent fails recognize this

problem. The configuration of probe 40 of the ‘349 patent cannot fairly be said to have a distal arm at a determined distance from an opposing portion nor can it be said that there is any teaching or suggestion to modify probe 40 to simulate this feature of claim 3.

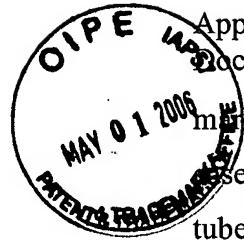
Accordingly, the ‘349 patent does not teach or suggest the arrangement of the conductors within the frame and exit of such conductors through a proximal arm, and the ‘349 patent does not teach or suggest modifications of the probes taught therein. Therefore, the ‘349 patent does not teach or suggest all of the limitations of claim 3 as required to establish a *prima facie* case of obviousness. The ‘008 patent does not cure the deficiencies of the ‘349 patent in this regard. Furthermore, the ‘349 patent does not contemplate the placement of the probe over the lip or cheek of a patient, much less potential issues associated therewith and configurations of probes to address such issues. Thus it cannot be legitimately said that there is a specific suggestion or teaching to modify the configuration of the probe 40. For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of this 35 USC § 103(a) rejection.

Claims 11-13 are rejected under 35 USC § 103(a) as obvious over the ‘349 patent, and further in view of U.S. Patent No. 5,619,992 (‘992 patent). Applicants respectfully traverse. Claims 11-13 are construed to contain the limitations of claim 1. Applicants reiterate that several key elements of claim 1, and therefore, claims 11-13 are missing from the ‘349 patent. The probe of the ‘349 patent lacks a proximal arm and distal arm distinction, it lacks conductors that pass through the frame of the probe and exit out the distal arm; and it lacks a configuration where there is a determined distance between the proximal and distal arms. The ‘992 patent does not cure these deficiencies. Neither the ‘349 patent nor the ‘992 patent contemplate the use of probes on the lip or cheek of a patient, or the benefits of doing so. Thus, the ‘349 patent and ‘992 patent, either alone or in combination, fail to teach all of the elements of claims 11-13, which is required to establish a *prima facie* case of obviousness. Applicants respectfully request reconsideration and withdrawal of this 35 USC § 103(a) rejection.

Claims 14-17 are rejected under 35 USC § 103(a) as being obvious over the ‘349 patent and in further view of U.S. Patent No. 6,190,327 (‘327 patent). Applicants respectfully traverse and incorporate the remarks made above in response to the obviousness rejections. The distinctions between the claim 1 and the ‘349 patent apply also to independent claims 14 and 17. In addition, claim 14 comprises the limitation of a means for attaching a capnography sampler or a cannula device for supplying oxygen. Claim 17 comprises the limitation of a capnography sampler or cannula device attached to the pulse oximeter probe.

The ‘327 patent discloses a CO₂ detector and pulse oximeter detector system. The ‘327 system comprises a detector that comprises a pulse oximeter conductively connected to a detector and a CO₂ sensor module separate from the pulse oximeter probe that is also conductively connected to the detector. The CO₂ sensor comprises a tube into which a person must exhale in order for the CO₂ detector. There is no teaching or suggestion in the cited references of a pulse oximeter probe that comprises a capnography device or a oxygen delivery cannula attached to or integral to such probe nor is there any suggestion to modify the probe of the ‘349 patent or system of the ‘327 patent to achieve such a configuration. Based on this reason alone, the cited references fail establish a *prima facie* case of obviousness for claims 14 and 17.

Applicants again point out that neither of the references contemplate a pulse oximeter probe designed for use on a cheek or lip. In view of the obstacles of using the ‘349 patent probe on the lip and cheek, it would be even more inappropriate to use the ‘349 patent probe for this purpose in the ‘327 patent system, since the CO₂ probe is designed for blowing and would interfere and obstruct placement of a lip/cheek probe. The probe of claim 14 and claim 17 define a probe suitable for comfortable, safe use of a lip/cheek probe which as noted in the subject application allows for accurate plethysmography readings from a central source site. In addition, the implementation of a capnography sampler or cannula for oxygen deliver provides additional benefit of allowing the acquisition of additional useful patient information, or delivering needed medical treatment, respectively. An ‘all in one’ device as defined in claims 14 or 17 is a



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marked improvement over having separate devices for such purposes. It allows for the ease of use and avoids the adding on of more and more devices with separate wires and tubes. This makes the patient more comfortable, reduces the possibility of entanglement of wires and tubes, and allows the medical care personnel to more safely and efficiently care for a patient.

Neither the '349 patent nor the '327 patent teach all of the elements of claims 14 or claim 17 as required for obviousness. There is no suggestion to modify either of the cited references to achieve the elements of claims 14 and 17. Claims 15-16 are construed to contain the limitations of claim 14, and therefore are also not rendered obvious by the cited references. Applicants respectfully request that this 35 USC § 103(a) rejection be reconsidered and withdrawn.

Applicants believe that all claims are in a condition for allowance, and request that a Notice of Allowance be issued. Applicants invite the Examiner to call the undersigned if clarification is needed on any aspect of this response. In addition, the Applicants request that the Examiner call the undersigned to arrange a telephonic interview if the Examiner believes that not all grounds for rejection have been addressed and overcome.

Respectfully submitted,



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